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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/652,284	08/31/2000	Vi-En Choong	MBHB00-025	2923

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ROBIN M. SILVA
FLEHR HOHBACH TEST ALBRITTON & HERBERT LLP
FOUR EMBARCADERO CENTER. SUITE 3400
SAN FRANCISO, CA 94111

[REDACTED] EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
1639	/0

DATE MAILED: 11/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/652,284	CHOONG ET AL.	
Examiner	Art Unit	1639	
My-Chau T. Tran			

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 September 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-80 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z . | 6) <input type="checkbox"/> Other: _____ . |

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DETAILED ACTION

1. Applicant's amendment filed 9/18/02 in Paper No. 9 is acknowledged and entered.

Claims 1-4 and 64-68 are amended. Claims 76-80 are added. Claims 1-80 are pending.

Information Disclosure Statement

2. The information disclosure statement filed 6/27/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Withdrawn Rejections

3. The previous rejections under 35 U.S.C. 112, second paragraph for Claims 64-75, have been withdrawn in view of applicant's amendments and arguments.

4. All rejections are maintained because the amended claims have introduced new matters. Maintained rejections are set forth below along with response to arguments.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Maintained Rejections***Claim Rejections - 35 USC § 102***

1. Claims 1-2, 6-30, 33-46, 48-51 and 53-77 rejected under 35 U.S.C. 102(e) as being anticipated by Kayyem et al (US Patent 6,290,839 B1).

Kayyem et al. discloses an apparatus for electrical or electrochemical detection of molecular interactions in a sample solution (abstract; col. 2, line 26-36). The apparatus comprise of a supporting substrate (fig. 1C, ref. #30; col. 2, line 42), a plurality of porous, polymeric pads (fig. 1C, ref. #25; col. 2, line 28-29 and 49-50; col. 8, line 41-54), and a set of electrodes in contact with a plurality of porous, polymeric pads (fig. 1 (A-D), ref. #10 and 20; col. 2, line 28-29 and 42-43; col. 8, line 31-41). The electrodes are arranged to address a subset of test sites (fig. 1 (A-F); col. 2, line 40-42). Each output electrode is in electrochemical contact with an input electrode (col. 2, line 33-37). The linker (ref. #106, fig. 3A) is in contact with the polymeric pads (ref. #107, fig. 3A) and the probe molecules (ref. #100, fig. 3A) immobilized to the linker (col. 3, line 1-5; col. 6, line 4-13 and 39-46; col. 65, line 50-57). The apparatus further comprise of a reference electrode, a means for producing an electrical signal, a means for detecting changes in the electrical signal (col. 65, line 66-67 and continue to col. 66, line 1-9), and an electrolyte solution in contact with the polymeric pads (col. 2, line 27-31; col. 11, line 1-2). The molecular interactions between the immobilized probe molecules and target molecules are detected (col. 1, line 61-67 and continue to col. 2, line 1-2). The preferred electrodes are known in the art and include gold and platinum, which are known as conductive material (col. 8, line 7-17). It is also known in the art that electrodes are also comprise of an insulating material such as glass and the insulating material is the supporting substrate (col. 58, line 6-13; fig. 1 (A-

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E), ref. #30). The linker moieties comprise of thiol linkers (col. 23, line 12-13; col. 25, line 3-20). The probe molecules are nucleic acids or peptides (col. 23, line 66-67 and continue to col. 24, line 1-5 and 26-65). The probes are covalently attached to the linker and are in contact with the electrode (col. 21, line 26-29).

Kayyem et al. further teaches the method for electrical detection that includes cyclic voltammetry (Abstract; col. 68, line 55-67 and continue to col. 69, line 1-5). The method steps are applying and detecting the first electrical signal, exposing the sample mixture containing the target molecule, applying and detecting a second electrical signal, comparing and determining the difference of the first and second electrical signal (col. 9, line 34-52; col. 74, line 58-61).

Claim Rejections - 35 USC § 103

2. Claims 3-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kayyem et al (US Patent 6,290,839 B1) in view of Roberts et al. (US Patent 5,958,791).

Kayyem et al. discloses an apparatus for electrical or electrochemical detection of molecular interactions in a sample solution (abstract; col. 2, line 26-36). The apparatus comprise of a supporting substrate (fig. 1C, ref. #30; col. 2, line 42), a plurality of porous, polymeric pads (fig. 1C, ref. #25; col. 2, line 28-29 and 49-50; col. 8, line 41-54), and a set of electrodes in contact with a plurality of porous, polymeric pads (fig. 1 (A-D), ref. #10 and 20; col. 2, line 28-29 and 42-43; col. 8, line 31-41). The electrodes are arranged to address a subset of test sites (fig. 1 (A-F); col. 2, line 40-42). Each output electrode is in electrochemical contact with an input electrode (col. 2, line 33-37). The linker (ref. #106, fig. 3A) is in contact with the polymeric pads (ref. #107, fig. 3A) and the probe molecules (ref. #100, fig. 3A) immobilized to

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the linker (col. 3, line 1-5; col. 6, line 4-13 and 39-46; col. 65, line 50-57). The apparatus further comprise of a reference electrode, a means for producing an electrical signal, a means for detecting changes in the electrical signal (col. 65, line 66-67 and continue to col. 66, line 1-9), and an electrolyte solution in contact with the polymeric pads (col. 2, line 27-31; col. 11, line 1-2). The molecular interactions between the immobilized probe molecules and target molecules are detected (col. 1, line 61-67 and continue to col. 2, line 1-2). The preferred electrodes are known in the art and include gold and platinum, which are known as conductive material (col. 8, line 7-17). It is also known in the art that electrodes are also comprise of an insulating material such as glass and the insulating material is the supporting substrate (col. 58, line 6-13; fig. 1 (A-E), ref. #30). The linker moieties comprise of thiol linkers (col. 23, line 12-13; col. 25, line 3-20). The probe molecules are nucleic acids or peptides (col. 23, line 66-67 and continue to col. 24, line 1-5 and 26-65). The probes are covalently attached to the linker and are in contact with the electrode (col. 21, line 26-29).

Kayyem et al. further teaches the method for electrical detection that includes cyclic voltammetry (Abstract; col. 68, line 55-67 and continue to col. 69, line 1-5). The method steps are applying and detecting the first electrical signal, exposing the sample mixture containing the target molecule, applying and detecting a second electrical signal, comparing and determining the difference of the first and second electrical signal (col. 9, line 34-52; col. 74, line 58-61).

The apparatus of Kayyem et al. differs from the claimed invention in failing to disclose that the output and input electrodes are interdigitated.

Roberts et al. discloses an apparatus that the output and input electrodes are interdigitated (Abstract; col. 6, line 10-13; col. 7, line 66-67 and continue to col. 8, line 1). Roberts et al. also

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teach that the reference electrode is comprised of silver/silver chloride (col. 23, line 17-18 and claims 15 and 40). The support substrate comprises ceramic (col. 18, line 12-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus of Kayyem et al. by interdigitating the output and input electrodes as taught by Roberts et al. for the advantage of increasing signal detection such as increasing signal-to-noise ratio and decreasing ohmic signal losses (col. 8, line 2-10). The feature of interdigititation of the microelectrodes constitutes obvious variations in parameters that are routinely modified in the art. The art (Robert et al., col. 8, line 2-37) has shown that microelectrodes fabricated in an interdigitated array have inherent advantages in signal detection over more conventional electrode configurations.

The features of the dependent claims are either specifically described by the reference (e.g. streptavidin/biotinylated or ferrocene) or constitute obvious variations in parameters which are routinely modified in the art (e.g. choice of particular probe or detection device) and which have not been described as critical to the practice of the invention.

3. Claims 1-63 rejected under 35 U.S.C. 103(a) as being unpatentable over Sosnowski et al. (US Patent 6,051,380) in view of Roberts et al. (US Patent 5,958,791).

Sosnowski et al. teaches an apparatus for electrical or electrochemical detection of molecular interactions in a sample solution (Abstract; col. 7, line 13-20). The apparatus comprise of a supporting substrate (fig. 1), a plurality of porous, polymeric pads (fig. 2, ref. #22; col. 21, line 54), and a set of electrodes in contact with a plurality of porous, polymeric pads (fig. 1 and 2, ref. #12; col. 9, line 41-48; col. 21, line 37-40). The electrodes are comprised of a

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conductive material and insulating material (col. 21, line 42-48). The electrodes are arranged to address a subset of test sites (fig. 3). Each output electrode is in electrochemical contact with an input electrode (col. 29, line 13-25). The polymeric pads comprise of polyacrylamide gel (col. 25, line 56-63). An electrolyte solution is in contact with the polymeric pads (col. 15, line 47-55; col. 38, line 46-50). The linker is in contact with the polymeric pads and the probe molecules immobilized to the linker (fig. 4 and 19; col. 30, line 34-36). The apparatus further comprise of a means for producing an electrical signal, a means for detecting changes in the electrical signal (col. 33, line 26-42). The molecular interactions between the immobilized probe molecules and target molecules are detected (col. 7, line 61-67 and continue to col. 8, line 1-8). The probe molecules are nucleic acids or peptides (col. 9, line 14-32). The probes are covalently attached to the linker and are in contact with the electrode (fig. 19).

The apparatus of Sosnowski et al. differs from the claimed invention in failing to disclose that the output and input electrodes are interdigitated.

Roberts et al. discloses an apparatus that the output and input electrodes are interdigitated (Abstract; col. 6, line 10-13; col. 7, line 66-67 and continue to col. 8, line 1). Roberts et al. also teach that the reference electrode is comprised of silver/silver chloride (col. 23, line 17-18 and claims 15 and 40). The support substrate comprises ceramic (col. 18, line 12-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus of Sosnowski et al. by interdigitating the output and input electrodes as taught by Roberts et al. for the advantage of increasing signal detection such as increasing signal-to-noise ratio and decreasing ohmic signal losses (col. 8, line 2-10). The feature of interdigititation of the microelectrodes constitutes obvious variations in parameters that

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are routinely modified in the art. The art (Robert et al., col. 8, line 2-37) has shown that microelectrodes fabricated in an interdigitated array have inherent advantages in signal detection over more conventional electrode configurations.

The features of the dependent claims are either specifically described by the reference (e.g. streptavidin/biotinylated or ferrocene) or constitute obvious variations in parameters which are routinely modified in the art (e.g. choice of particular probe or detection device) and which have not been described as critical to the practice of the invention.

New Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-80 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The instant claims recite an apparatus comprising a substrate, a plurality of porous polymeric pads, a set of input electrodes, a set of output electrodes, a plurality of linker, a plurality of probe, a signal generator, and a detector for the detection of molecular interactions between immobilized probe and target in a sample solution.

The recitation ‘wherein each input electrode is arranged such that a first portion of the input electrode is in contact with a test site and a second portion of the input electrode is in contact with a different test site’ and ‘wherein each output electrode is arranged such that a first portion of the output electrode is in contact with a test site and a second portion of the output electrode is in contact with a different test site’ claimed in claims 1 and 2, has no clear support in the specification and the claims as originally filed. The specification in page 11 disclosed that the ‘...the set of input electrodes being arranged so that each input electrode addresses a subset of test sites’ (lines 2-3) and ‘...the set of output electrodes being arranged so that each output electrode addresses a subset of test sites’ (lines 4-5) is not support for ‘...each input electrode is arranged such that *a first portion* ... in contact with a test site and *a second portion* ... in contact with a different test site’ and ‘... each output electrode is arranged such that *a first portion* ... in contact with a test site and *a second portion* ... in contact with a different test site’. Because the broad limitation of the specification recites that the electrodes addresses a subset of test sites, does not support the narrow limitation of the claim, which recites that there is two portions to the electrode. Therefore, the specific limitation that the electrode has two portions would not be encompassed by the scope of the invention as originally disclosed in the specification.

Further, the recitation of ‘a first electrode chosen from the set of input electrodes, and a second electrode chosen from the set of input electrodes’ claimed in claim 78; ‘each electrode in the set of input electrodes defines an x coordinate, and each electrode in the set of output electrodes defines a y coordinates’ claimed in claim 79; and ‘each electrode in the set of output electrodes defines an x coordinate, and each electrode in the set of input electrodes defines a y

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coordinates' claimed in claim 80, has no clear support in the specification and the claims as originally filed. No supports are found for these specific limitations in the specification.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

Response to Arguments

8. Applicant's arguments filed 9//24/02 have been fully considered but they are not persuasive. Because applicant argument are moot since they are based on the amended claims that have introduced new matter.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
November 27, 2002



PADMASHRI PONNALURI
PRIMARY EXAMINER